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09/651,563	08/29/2000	Tongtong Wang	210121.478C10	1478

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EXAMINER
BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
1631	11

DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/651,563	Applicant(s) Wang et al
	Examiner Michael Borin	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 13, 2001*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above, claim(s) *1-3 and 11-60* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *4-10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *2,4,6*
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Status of Claims

1. Response to restriction requirements filed 6/14/01 and 9/13/01 is acknowledged. Applicant elected, without traverse, Group III.1, claims 4-10 drawn to drawn to polynucleotides encoding polypeptide encoded by polynucleotide of SEQ ID 808, expression vectors and cells comprising the vector.

Claims 1-3, 11-60 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to non-elected groups.

Abstract

2. The abstract of the disclosure is objected to because it does not reflect the invention as elected. Correction is required.

Claim Objections

3. Claims 4-10 are objected because they do not reflect the elected subject matter. Applicant elected polynucleotide encoding polypeptide encoded by polynucleotide of SEQ ID 808. The claims do not reflect the elected subject matter. Amendment of the claims to read on the polynucleotide of SEQ ID 808 is requested.

Sequence Listing

4. The Sequence Listing filed was approved by STIC for matters of form.

Claim Rejections - 35 U.S.C. § 101/ 112-1

5. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement

thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

5. Claims 4-10 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claims are not supported by a substantial utility as the assertion of using of the elected oligonucleotides for cancer diagnostics is not supported by specification. There is no evidence in the specification that expression of the elected oligonucleotides is specific to lung cancer. The mere mention that the polynucleotides encode "lung tumor protein" and a "lung tumor protein" is a protein which is expressed in lung tumor cells at a level at least two-fold as compared to normal tissue, does not provide sufficient evidence that such proteins (and polynucleotides which encode them) are indeed correlate to the particular disease, lung cancer. The type of "a normal tissue" is not identified. Hence, the meaning of "at least two fold greater" is not clear, as well as it is no evidence that the information about the polypeptides of the invention (and polynucleotides encoding them) was obtained from a substraction libraries. There are no control experiments demonstrating that selected sequences can indeed be used as markers of lung cancer. Further, there is no evidence that particular polypeptides disclosed in the specification are overexpressed in tumor lung cells and is in any way related to lung

cancer development. In addition, the claims are drawn not only to polynucleotide of SEQ ID No 808 , but also to polynucleotides encoding at least 15 residues of a lung tumor protein, the latter being encoded by polynucleotide SEQ ID 808, or to polynucleotides encoding variants of said lung tumor protein. There is no information that fragments or variants of a "lung tumor protein" have an asserted utility. The invention is an invitation for further basic research to study whether and which of the encoded proteins and variants thereof are "lung tumor proteins" and whether they, or polynucleotides encoding thereof are suitable for diagnostics of the particular cancer. The need for such research clearly indicates that the method is not disclosed as to a currently available or substantial utility. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. Identifying use of the claimed polypeptide would require carrying out further research. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. In addition, there is no well established utility known for polypeptide as claimed. Consequently, the claimed subject matter is not supported by a substantial or well established utility.

Note, because the claimed invention is not supported by a substantial utility for the reasons set forth above, credibility has not been assessed.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

6. Claims 4-10 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a substantial or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4-10 are rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is made for the following reasons:

A. The terms "complement" and "complementary" used in claims 4,5,8 are vague and indefinite. The metes and bounds of the claim are unclear since the applicant

fails to point out what amount of polynucleotide variation would be encompassed by the sequences that are complementary. The specification and claims do not indicate what distinguishing attributes are shared by members of genus of polynucleotides encompassed by the term.. For example, is the term complementary defined as a sequence which is identical through the entire length? Is there any limit to number of substitutions, deletions, insertions and/or additions that may be made in which nucleic sequences can still be considered complementary? Can a nucleotide sequence which matches only a portion (e.g., a primer) be considered complementary?

B. The phrase "moderately stringent condition" used at the end of claim 7, is not clearly defined in the specification.

Claim Rejections - 35 USC § 102.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. Claims 4,5,7,8,9,10 are rejected under 35 U.S.C. 102(e) as anticipated by US Patent 6146877.

US Patent 6146877 teaches polynucleotides encoding progression elevated gene-3 (PEG-3) protein (SEQ ID No. 3 in the reference). Said protein, as can be seen from the attached sequence allignment, reads on a protein having at least 15 residues of a protein encoded by polynucleotide SEQ ID No. 808 and having certain variations, such as additions, insertions and substitutions.

Further, as the referenced sequence has continuous stretches matching SEQ ID No. 808, it would be expected to hybridize to SEQ ID No. under moderately stringent conditions, or be complementary to SEQ ID No. 808, absent evidence to the contrary. Consequently, the referenced sequence also reads on the products of claims 7,8.

Conclusion.

9. No claims are allowed

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

November 28, 2001

mlb